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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/156,804	09/17/1998	PATRICK KALTENBACH	10980096-1	1533

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AGILENT TECHNOLOGIES, INC.
INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT.
P.O. BOX 7599
M/S DL429
LOVELAND, CO 80537-0599

EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

24

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-24

Office Action Summary

Application No.

09/156,804

Applicant(s)

KALTENBACH ET AL.

Examiner

P. Kathryn Bex

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,25,26,28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,25,26,28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Applicant's cancellation claim 29 is acknowledged and has been entered into the record.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 20, 2002 has been entered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a plurality of separation units" and the "single reservoir adapted to contain a liquid for introduction into the micro-channels of each separation unit", as recited in claims 1, 25, and 28, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The current Figures show the reservoir unit 104 in connection to a *single* chip-shaped separation unit 102, not a plurality of separation units.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12, 25-26, 28, 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Examiner maintains that the language of a claims 1, 25 and 28 which recite, *plurality* of separation units, and single reservoir unit containing a liquid for introducing into *the micro-channel of each separation unit*, clearly indicates that a plurality of separation units are *simultaneously* combined with the single reservoir, even though this is apparently not what Applicant has intended the claims to indicate. Moreover, a reservoir unit which is simultaneously coupled to a plurality of separation units, is not supported by the instant specification. Additionally, Figures 1-2, 7B and 8, clearly indicate the use of a *single separation* unit connected to the reservoir unit. This same reasoning is applicable to claims 25 and 28.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12, 25-26, 28, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, the disclosure, a *plurality* of separation units and a single reservoir unit containing a liquid for introducing into *the micro-channel of each separation unit*, creates confusion and uncertainty as to what Applicant is trying to claim. This recitation of a reservoir that contains liquid for introduction into the micro-channels of the separation units conflicts with the wherein clause of the claim, which describe the coupling of the reservoir unit to each separation unit in *succession*. This deficiency was found in claims 25 and 28.

Claim Rejections - 35 USC § 102

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1, 3, 25, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyake *et al* (USP 5,519,635).

Miyake *et al* teach a apparatus for chemical analysis with multiple detachable separation units 11-13. The system of Miyake teach the coupling of a reservoir unit via connection 4 to various separation units. These separation units can be one of the types shown in Figures 6-8, thereby having different channel lengths (column 9, line 65- column 10, lines 18). The addition of the liquid into the separation units can be done either sequentially or in parallel (Fig. 1, 11). The separation unit comprising inlets and outlets and a plurality of channels (Fig. 2). The system comprising a driving unit 52-55 for supplying or driving the liquid from reservoir to the micro-channel of each separation unit.

10. Claims 1, 3, 25, 28 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow *et al* (USP 5,989,402).

Chow *et al* teach a micro-fluidic separation system comprising replaceable separation units 14. The separation units having inlets and outlets, and micro-fluidic channel. Chow *et al* disclose that the separation units can must include at least one micro-scale channel, but the configuration of the channels can exist in a number of formats (column 5, lines 3-27). Therefore

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Chow *et al* do teach the use of separation units of with channels of different configurations, i.e. different lengths. The system comprising a single reservoir unit having a plurality of reservoirs 24 containing a liquid and an external power unit coupled to a probe which applies a driving force from the reservoir to the micro-channel of the separation device. Additionally, the system comprising a support plate 206. The system further comprising a membrane or gasket placed on the surface of the reservoir unit (column 11, lines 15-20)

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-9, 25-26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loux *et al* (WO 97/44132) in view of Swedberg *et al* (USP 5,571,410).

Loux *et al* teach a modular housing assembly for micro-machined fluid handling

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structure comprising the use of a plurality of separation units 22 (page 11, lines 2- 16), each having micro-channels (not shown) ,inlet and outlet ports 60, 62, 64. Loux *et al* teach a single reservoir unit 24 comprising a plurality of reservoirs which introduce liquid into the inlet of the separation chamber via tubes, i.e., 51 which communicates with the interior channels of the separation unit 22. The system having pins 34, 36 and a clamp 48, such that the assembly is easily disassembled with the reservoir plate being easily separated from the micro-machined separation unit 22. Additionally, the system comprises a modular heater 14 assembly. The reservoir unit having a membrane or seals captured between the reservoir plate and the separation unit to prevent leakage of the fluid. The system includes a power unit connected to the reservoir unit to supply pneumatic pressure to the reservoirs (Figs. 2, 5). Loux *et al* do not disclose a separation device comprising a first and second half. Swedberg *et al* teach a separation unit 2 having a planar first an second half, wherein at least one of the halves has the micro-channel 10 formed thereon (Figs. 4-17C). Moreover, Swedberg *et al* disclose various separation units with different channel lengths and depths for different separation analysis (Figs. 2, 7A, 10, 16B).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in either systems of Loux *et al* the separation unit, as taught by Swedberg, in order to derive a sample processing compartment featuring enhanced symmetry and axial alignment (column 5, lines 31-36).

14. Claims ~~2~~, 4-9, 26, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake *et al* (USP 5,519,635) in view of Swedberg *et al* . (USP 5,571,410).

Miyake *et al* as previously discussed above, do not disclose wherein the separation unit is formed from a planar first and second half, wherein at least one of the halves has the channel formed thereon. Swedberg *et al* teach a separation unit 2 having a planar first and second half, wherein at least one of the halves has the micro-channel 10 formed thereon (Figs. 4-17C). Moreover, Swedberg *et al* disclose various separation units with different channel lengths and depths for different separation analysis (Figs. 2, 7A, 10, 16B).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in either systems of Miyake *et al* the separation unit, as taught by Swedberg, in order to derive a sample processing compartment featuring enhanced symmetry and axial alignment (column 5, lines 31-36).

15. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake *et al* (USP 5,519,635) or Loux *et al* (WO 97/44132) in view of Swedberg *et al* . (USP 5,571,410) as applied to claim 26, and further in view of Kaltenbach *et al* . (USP 5,641,400).

Miyake *et al* or Loux and Swedberg as disclosed above, do not teach an apparatus comprising a peltier plate operatively and modularly coupled to the support plate for controlling the temperature thereof. However, Kaltenbach does teach peltier plates for coupling to the support plate for controlling the temperature thereof (column 20 lines 37-67 and column 21 lines 1-37, Figures 9A-10B).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Miyake *et al* or Loux *et al* and Swedberg, peltier plates coupled to the support plate, in order to influence many of the physical and chemical parameters involved in separation techniques and decrease the time needed to perform the

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separation. The temperature can affect the sample stability, buffer viscosity, chemical equilibria, pH and the resulting migration time for a given chemical species (column 3 lines 9-21).

16. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loux *et al* (WO 97/44132) in view of Swedberg *et al* (USP 5,571,410) as applied to claim 26, and further in view of Kaltenbach *et al* (USP 5,641,400).

Loux and Swedberg as disclosed above, do not teach an apparatus comprising a peltier plate operatively and modularly coupled to the support plate for controlling the temperature thereof. However, Kaltenbach does teach peltier plates for coupling to the support plate for controlling the temperature thereof (column 20 lines 37-67 and column 21 lines 1-37, Figures 9A-10B).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Loux *et al* and Swedberg, peltier plates coupled to the support plate, in order to influence many of the physical and chemical parameters involved in separation techniques and decrease the time needed to perform the separation. The temperature can affect the sample stability, buffer viscosity, chemical equilibria, pH and the resulting migration time for a given chemical species (column 3 lines 9-21).

Response to Arguments

17. Applicant's arguments filed March 20, 2002 have been fully considered but they are not persuasive. With respect to the previous rejection of claims 1-12, 25-26, 28-30 under 35 U.S.C. 112, first paragraph, Applicant argues that the instant invention is drawn to a reservoir unit that can be operatively and modularly connected to each separation unit in succession. However, Examiner believes that the claims as *currently written* do not reflect such a

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configuration. The instant claims 1, 25, 28, part (b) recite "a single reservoir unit...comprised of a reservoir that contains a liquid for the introduction into the micro-channels of the separation units"; this recitation indicates that the reservoir unit is communication with each of the separation units *simultaneously*. Therefore the objection to the drawings and the 35 U.S.C. 112, first paragraph rejections are maintained.

In response to the rejection of claims 1, 3, 25, 28 and 30 under 35 U.S.C. 102(b) as being anticipated by Miyake *et al* (USP 5,519,635), Applicant argues that Miyake *et al* do not teach separation units with microchannels of different lengths, since the plurality of separation units employed are identical in construction. Examiner points to the different embodiments of the separation devices shown in Figures 6-8 have a different internal construction, i.e. different channel lengths for mixing (column 9, line 65- column 10, lines 18). Similarly, with respect to the rejection of claims 1, 3, 25, 28 and 30 under 35 U.S.C. 102(e) as being anticipated by Chow *et al* (USP 5,989,402). Applicant argues that Chow *et al* (USP 5,989,402) do not teach separation units with micro-channels of different lengths. Examiner does not agree since Chow *et al* do disclose the invention being used with different micro-fluidic device which have different channel configurations, i.e. different lengths (column 5, lines 20-25).

Conclusion

18. No claims allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to

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3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
May 17, 2002

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700